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**Title:** Development of the AACN Sedation Assessment Scale for Critically Ill Patients

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**Authors:**

- Marla J. De Jong, RN, MS, CCNS, CCRN, CEN, Major  
PhD Candidate  
University of Kentucky, School of Nursing  
Lexington, KY  
Home Telephone: 859-223-7265  
Office: N/A – full-time student  
Fax: 859-223-7265  
Cell Telephone: 859-576-4521  
E-mail: mdejong@aol.com
- Suzanne M. Burns, RN, MSN, RRT, ACNP, CCRN, FAAN, FCCM  
Professor of Nursing, Acute and Specialty Care  
APN 2, Medicine/MICU  
McLeod Hall School of Nursing  
Box 800782  
University of Virginia Health System  
Charlottesville, VA 22903-3395  
Phone: 434-924-2259  
FAX: 434-982-1809  
E-mail: smb4h@virginia.edu
- Margaret L. Campbell, RN, MSN, FAAN  
Nurse Practitioner, Palliative Care and Clinical Ethics  
Detroit Receiving Hospital  
Nursing Administration  
4201 St. Antoine  
Detroit, Michigan 48201  
Phone: 313-745-3271 (office)  
FAX: 313-745-3637  
E-mail: mcampbe3@dmc.org
- Marianne Chulay, RN, DNSc, FAAN  
Consultant, Clinical Research and Critical Care Nursing  
505 N. Boundary St.  
Chapel Hill, NC 27514  
Phone: 919-932-9972  
E-mail: Chulay@aol.com

20050314 052

- Mary Jo Grap, RN, PhD, ACNP, FAAN  
Professor  
School of Nursing  
Virginia Commonwealth University  
PO Box 980567  
Richmond, VA 23298-0567  
Phone: 804-828-0723  
E-mail: [mjgrap@vcu.edu](mailto:mjgrap@vcu.edu)
- Lynelle N.B. Pierce RN, MS, CCRN  
Clinical Nurse Specialist, Critical Care  
University of Kansas Hospital  
Department of Nursing, Wescoe  
3901 Rainbow Boulevard  
Kansas City, KS 66160-7220  
Telephone: 913-588-4448  
E-mail: [lpierce@kumc.edu](mailto:lpierce@kumc.edu)
- Terri Simpson, RN, PhD  
Associate Professor  
School of Nursing, Biobehavioral Nursing & Health Systems Department  
University of Washington  
Box 357266  
Seattle, WA 98195-7266  
Phone: 206-221-6327  
E-mail: [tsimpson@u.washington.edu](mailto:tsimpson@u.washington.edu)

**Contact Author:** Marla J. De Jong  
3697 White Pine Dr.  
Lexington, KY 40514  
Home: (859) 223-7265  
FAX: (859) 223-7265  
E-mail: [mdejong@aol.com](mailto:mdejong@aol.com)

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Clinicians commonly sedate critically ill patients to facilitate patient-ventilator synchrony, relieve anxiety, promote sleep or rest, prevent self-harm, induce amnesia, alleviate agitation, promote hemodynamic stability, and reduce intracranial pressure. Sedatives should be administered to achieve predetermined endpoints, as both insufficient sedation and over-sedation may lead to adverse patient outcomes. Yet, a major limitation of most currently available sedation assessment scales is the narrow focus on a single domain, usually consciousness or agitation.<sup>1</sup>

In August 2002, a group of critical care experts met in Nashville, TN for a consensus conference on sedation assessment. The conference, Phase 1 of a 3-Phase project, was the result of a collaborative effort between the American Association of Critical-Care Nurses (AACN), Abbott Laboratories, and Saint Thomas Health System (Nashville, TN) and was designed to address the critical need for a valid and reliable sedation assessment scale for use in critically ill patients.

To obtain a broad perspective on sedation assessment and management requirements in critical care practice, individuals with clinical practice expertise in medical, surgical, cardiovascular, neurosurgical, pediatric, and adult critical care nursing were invited to participate in the consensus conference. Participants were experts in sedation management and represented hospital practice throughout the United States. In addition, members were selected based on their expertise regarding pain management, anxiety/fear, sleep, patient-ventilator synchrony, delirium, clinical pharmacology, and sedation scale development – concepts that are highly relevant to sedation assessment and management.

During the consensus conference, a series of questions was posed to participants and served as the basis for the development of a new sedation assessment tool. Questions included the following:

- Are the available sedation assessment scales adequate for use in critically ill patients? Is there a need for a new sedation assessment scale?
- What is needed to improve sedation assessment in the critically ill patient?
- What subscales or domains should be included in a sedation assessment scale?
- What are the challenges to assuring that critically ill patients' sedation needs are adequately addressed?

A summary of the responses to these questions has been described in a previous publication.<sup>1</sup> Importantly, participants recommended development of a new sedation assessment scale consisting of multiple domains that represent the goals of sedation therapy. Suggested domains included consciousness, patient safety/agitation, anxiety, sleep, and patient-ventilator synchrony.

Phase 2 of the project was to develop the American Association of Critical-Care Nurses (AACN) Sedation Assessment Scale, a new scale for use with critically ill patients who require either continuous or intermittent sedation. Following the consensus conference, experts were identified for each suggested domain. As requested, each expert defined the concept represented in the domain, summarized validity and reliability data from previously developed measures of the concept, and recommended the best objective and subjective indicators of the concept. These recommendations were used to create the five subscales, one for each domain, of the AACN Sedation Assessment Scale.

To determine face and content validity of the AACN Sedation Assessment Scale, the original members of the consensus conference, as well as five additional critical care experts,

reviewed the proposed AACN Sedation Assessment Scale. For each subscale, individuals responded to numerous questions to determine the degree to which the domains of the scale represent sedation assessment needs of critically ill patients and whether or not the proposed indicators appear to measure the concept. Reviewers were asked to use the draft AACN Sedation Assessment Scale in clinical practice prior to responding to the evaluation questions, if feasible. Minor revisions to the scale were made based on the reviews.

The purpose of this paper is to present the outcome of Phase 2 of the sedation assessment project, namely, development of a new sedation assessment scale for critically ill patients. The authors define each of the five scale domains and present information on how indicators were selected to assess each domain, while acknowledging that psychometric testing is required before the AACN Sedation Assessment Scale can be recommended for clinical practice. A future publication will include results of psychometric testing, rationale for any needed modifications of the scale, and detailed directions for using and scoring the scale.

### **Sedation Scale Domains**

#### **Consciousness**

Consciousness is awareness of oneself and the environment<sup>2</sup> and has discrete, inter-related components. Wakefulness or arousal is a necessary pre-condition for consciousness. The conscious person selectively perceives sensations, attending to some while filtering out others. A number of events can be held in working memory, a component that is strongly related to attention. Memories can be recovered and invoked when processing information. Cognition is the highest level of consciousness and involves synthesis of all previously listed components.<sup>3</sup>

Impaired cognition and decreases in consciousness may occur as a consequence of critical illness or injury. An example of cognitive impairment is delirium, an acute, reversible

organic mental syndrome of global mental impairment resulting from severe medical illness.

Common syndromes of impaired consciousness include stupor, coma, persistent vegetative state, and brain death.

Delirium has an acute onset and fluctuating course and impairs a person's ability to receive, process, store, or recall information.<sup>4</sup> Delirium is relatively common in Intensive Care Unit (ICU) patients related to numerous clinical conditions, substance intoxication or withdrawal, use of medications, or a combination of these factors.<sup>5</sup> Although delirium has been erroneously termed ICU psychosis, delirium is the more accurate term.

Stupor and coma are characterized by impairment of the arousal system. In stupor, the patient arouses only with strong verbal or tactile stimuli, awakens briefly, and then lapses back into a sleep-like state after the stimulation stops. In coma, the patient cannot be roused to consciousness. Numerous conditions produce stupor or coma, including structural lesions, metabolic derangements, inflammatory conditions, toxins, drugs, and neurodegenerative diseases.<sup>6</sup>

Patients who are in a persistent vegetative state have the capacity for wakefulness, but not for awareness. The patient exhibits sleep and wake cycles and can be aroused by sound or touch, but cannot interact or carry out any motor act that requires planning or cognition. There is no evidence of recognition of self or the environment.<sup>7</sup> Brain death is the cessation of all brain function, including the brain stem, and is characterized by three cardinal findings: coma, absence of brainstem reflexes, and apnea.<sup>8</sup>

### ***Assessment of Consciousness***

The neurological exam is the reference standard for measuring consciousness. The degree of obtundation is best described by the patient's spontaneous activity and responsivity to

stimuli.<sup>9</sup> Standardized documentation of consciousness through the use of scales is useful.

Coma scales provide severity information across levels of consciousness from fully awake and aware to stupor and coma.

The Glasgow Coma Scale (GCS)<sup>10</sup> is almost universally used to assess consciousness. This 15-point scale is comprised of three ordered items: motor response, verbal response, and eye opening. However, the GCS has not been used consistently, particularly in patients who are intubated or have orbital swelling preventing verbal response or ocular assessment.<sup>11,12</sup> Furthermore, there is a theoretical disadvantage to the three-dimensional assessment. The three motor activity scores, assumed to be independent variables, are summed to obtain the total score. However, this sum may not be valid because the motor activities covary. Lastly, eye opening does not equate with conscious awareness, since patients in a vegetative state and those with seizures may exhibit spontaneous eye opening.<sup>9</sup>

The Reaction Level Scale (RLS85)<sup>13</sup> was developed in Sweden for use in the ICU. The RLS85 is an 8-level ordinal scale that measures responsiveness to stimuli. Its anchors are “alert with no delay in response” and “unconscious with no responses.” Levels 2-7 of the RLS85 correspond with linear declines from conscious to lethargic/confused, stuporous, and unconscious. Unlike the GCS, the RLS85 can be used with patients who are intubated or have ocular swelling. Covarying variables are not added and the instrument compares favorably with the GCS.<sup>13,14</sup> The RLS85 is superior to the GCS because any change in RLS85 signifies a significant change in patient status.<sup>9</sup> Inter-observer agreement is better with the RLS85 than with the GCS.<sup>14</sup>



***Indicator of Consciousness in the AACN Sedation Assessment Scale***

The indicators for measuring consciousness in the AACN Sedation Assessment Scale (Table 1) are derived from the RLS85. The eight levels in the RLS85 were collapsed into five levels for the AACN Sedation Assessment Scale. The first three levels of the AACN Sedation Assessment Scale parallel the first three levels of the RLS85. To simplify the AACN Sedation Assessment Scale, the five levels of the RLS85 representing gradations of unconsciousness were collapsed into two levels.

**Agitation**

Agitation is most often described as excessive restlessness which is characterized by non-purposeful mental and physical activity due to internal tension and anxiety.<sup>15-17</sup> However, no clear, concise, and universally accepted definition pertains to ICU patients.<sup>17</sup> Agitated patients exhibit continual movement such as fidgeting, moving from side to side, pulling at dressings and bed sheets, and attempting to remove catheters or other tubes. The agitated patient is usually disoriented and cannot readily follow commands. Agitation occurs often in the critically ill<sup>18-20</sup> and may result in unplanned extubation, increased oxygen consumption, hemodynamic instability, and/or injury to self or care providers, as well as inability to participate in therapeutic interventions.<sup>21-23</sup>

The cause of agitation is often multifactorial and difficult to identify.<sup>16,17</sup> In the critical care setting, pain, hypoxia, drug effect, confusion, delirium, and substance or medication withdrawal are the most common precursors to agitation.<sup>24,25</sup> In addition, brain injury, ruptured aneurysm, thrombotic stroke, brain abscesses, hyper- and hypoglycemia, uremia, and elevated levels of lead and mercury have been associated with agitation.<sup>24</sup> The patient's exposure to loud

noise, bright lights, and continuous stimuli within the ICU environment may also contribute to agitation.<sup>26</sup>

### *Assessment of Agitation*

Subjective and objective approaches have been used to assess agitation. The two subjective approaches include clinician observations of the patient's physical activity and facial expressions. In general, clinicians assess for agitation as they subjectively observe the patient's physical activity, nonverbal behavior, and verbalizations. Consequently, findings of agitation may vary among clinicians due, at least in part, to confusion about the definition of agitation.<sup>17</sup> To minimize this variation, experts have developed scales to assess agitation; most also include measures of sedation. The most commonly used scales are the Ramsay Sedation Scale,<sup>27</sup> the Riker Sedation-Agitation Scale (SAS),<sup>20</sup> and the Richmond Agitation Sedation Scale (RASS).<sup>28</sup> Each of these scales evaluates the degree of agitation at one point in time and describes patient behavior. Most scales have been validated with critically ill patients. However, because there is no "gold standard" assessment of agitation, most scales have been validated against other sedation-agitation tools.

In addition to physical activity, clinicians examine the patient's facial expressions (grimacing) to assess agitation. Although examination of facial expressions has not been used specifically to evaluate agitation, it has been used with non-verbal adult and pediatric patients to assess pain or discomfort, potential causes of agitation.<sup>29-32</sup> Pediatric patients, like intubated adult patients, are often nonverbal and therefore unable to communicate their discomfort or distress. Thus, measures of distress used in the pediatric patient population may be appropriate for adults as well. Pediatric facial grimacing scales include evaluation of facial actions such as brow bulge, eyes squeezed shut, and nasolabial furrow.<sup>33</sup> The COMFORT Scale,<sup>29</sup> originally

designed to assess pain and sedation in intubated children, but more recently used with adults,<sup>30,34</sup> includes a 5-point measure of facial tension, rating facial muscles from totally relaxed to contorted and grimacing. Degree of facial expression is also associated with pain intensity in adults<sup>35,36</sup> and is the most commonly observed behavior related to procedural pain.<sup>37</sup> Facial expressions, specifically a wrinkled mouth or brow or eyes squeezed shut, have been used to assess pain in patients with advanced dementia.<sup>38</sup> While not specific to agitation, an evaluation of facial expressions may be an additional and meaningful measure of agitation.

Objective measures of agitation include hemodynamic stability, brain function (bispectral analysis), and physical activity (actigraphy). Agitation activates the sympathetic nervous system, causing the adrenal medulla to release catecholamines. Epinephrine enhances cardiac contractility, increases heart rate, and augments venous return to the heart, all of which increase cardiac output, blood pressure, and oxygen demand. In addition, norepinephrine elevates blood pressure through its constrictor effects on vascular smooth muscle. The increase in physical activity associated with agitation further increases heart rate, blood pressure, and oxygen demand. Two physiologic domains of the COMFORT Scale<sup>29</sup> address increases in heart rate and blood pressure related to pain and sedation and are appropriate markers for agitation. A 15% or greater change in heart rate or blood pressure is used to identify changes in physiologic status related to lack of comfort and is an appropriate level of change that can be recognized clinically.

The bispectral index (BIS) is calculated from electroencephalogram (EEG) data. A sensor on the patient's forehead transmits EEG data to a computer, which, in turn, translates the data into a single number ranging from 0 (absence of brain activity) to 100 (awake). The BIS was designed to monitor the depth of hypnosis during anesthesia and sedation.<sup>39,40</sup> Empirically derived from the EEGs of more than 5,000 anaesthetized patients, the BIS represents a bispectral

analysis of information from the cortical and subcortical areas of the brain that change with increasing amounts of stress and hypnotic drugs.<sup>41,42</sup> The BIS correlated with the Ramsay Scale in multiple studies.<sup>43,44</sup> However, associations among the BIS and other subjective and objective sedation scales vary among medical, surgical, and trauma patients.<sup>41,44-46</sup> In addition, excessive muscle movement introduces error and appears to undermine BIS reliability.<sup>44,47</sup> While the BIS may be an appropriate measure of depth of sedation in some patient populations, it may not accurately identify the restlessness or increased physical activity associated with agitation.

Actigraphy, a continuous measure of activity, was initially developed to measure activity during sleep. An actimeter is a small electronic device that when strapped to the wrist or ankle continuously senses and records minimal movements or activity during predetermined epochs for as long as several days. Actigraphy data are expressions of acceleration movement in numerical form. Actigraphy has been used to track circadian rest-activity cycles<sup>48</sup> and to identify states of wakefulness and sleep.<sup>49,50</sup> Wrist actigraphy has shown significant agreement with sleep-wake cycles<sup>51,52</sup> and provides objective indications of changes in depth of anesthesia or sedation during surgery and recovery.<sup>53</sup> More recently, actigraphy was shown to be highly correlated with subjective scales of agitation and sedation (RASS, COMFORT Scale), as well as with observed patient stimulation in adult critically ill subjects.<sup>54</sup> Although actigraphy, as currently measured, may not be useful in clinical settings for assessing moment-to-moment changes in agitation level, its usefulness as a research tool to objectively measure the physical activity component of agitation is promising.

### ***Indicators of Agitation in the AACN Sedation Assessment Scale***

Agitation is a behavior that results from a variety of causes and may be identified using a multi-factor assessment including body movement, patient noise, and patient verbalizations

(Table 1). Agitation is described as excessive restlessness; therefore, measures of body and facial movement, as well as verbalizations, are appropriate indicators. In addition, these indicators include commonly observed characteristics of agitation and are similar to those used in other measures of agitation in the critically ill.<sup>20,28,30</sup> Although physiologic parameters also may change and are part of any assessment of patient status, they are not exclusive to agitation and thus were not included.

### **Anxiety**

Anxiety is a “psychophysiological phenomenon experienced as a foreboding dread or threat to a human organism whether the threat is generated by internal, real or imagined dangers.”<sup>55, p.1</sup> Anxiety has been described as a subjective feeling of distress and anguish<sup>56</sup> that has affective, motivational, behavioral, and physiological components.<sup>56</sup> A key feature of anxiety is its subjective nature.

Anxiety exists along a continuum from a normal response associated with a perceived threat to a pathological anxiety disorder. Although anxiety is regarded as a motivational or adaptive process, persistent anxiety may produce dysfunctional responses and ensuing negative consequences. Both normal and pathological anxiety reactions have comparable cognitive, neurobiological, and behavioral components.<sup>57</sup>

Most relevant to ICU patients is state anxiety. State anxiety “refers to an empirical process or reaction which is taking place *now* at a given level of intensity.”<sup>58, p. 16</sup> Spielberger further conceptualized state anxiety as “a transitory emotional state or condition of the human organism that varies in intensity and fluctuates over time. This condition is characterized by subjective, consciously perceived feelings of tension and apprehension, and activation of the

autonomic nervous system.”<sup>59, p. 39</sup> Importantly, many ICU patients are anxious but do not meet diagnostic criteria for an anxiety disorder.

It is well-known that critically ill patients are often anxious.<sup>60-67</sup> The source of this anxiety is situational and is related to the ICU environment, diagnostic and therapeutic procedures, physical symptoms such as dyspnea or pain, healthcare costs, and concerns about disability, disfigurement, or death.

Physiologically, anxiety is not a benign phenomenon. Anxiety may trigger an overall sympathetic nervous system response which increases myocardial oxygen demand, induces myocardial ischemia, impairs ventricular function, alters heart rate variability, and compromises immune function. Data indicate that acute myocardial infarction (AMI) patients with elevated anxiety are more likely to develop in-hospital ventricular fibrillation, ischemia, and reinfarction.<sup>68</sup> Anxiety predicts recurrent cardiac events and mortality for cardiac patients<sup>69-71</sup> and has been associated with platelet aggregation,<sup>72</sup> recurrent thrombus formation,<sup>70</sup> and hyperventilation-induced coronary artery spasm.<sup>73</sup> Other consequences of unrelieved anxiety include increased dyspnea, increased oxygen consumption, and delayed ventilator weaning. Finally, anxiety during hospitalization has been linked to subsequent posttraumatic stress disorder.<sup>74</sup>

### *Assessment of Anxiety*

There are over 200 anxiety assessment instruments; however, no instrument has been distinguished as the “gold standard.” The State-Trait Anxiety Inventory (STAI), the anxiety subscale of the Brief Symptom Inventory (BSI), the Hospital Anxiety and Depression Scale (HADS), and the Profile of Mood States (POMS) are four valid and reliable self-report anxiety instruments that commonly have been used with critically ill patients. In addition, the Faces

Anxiety Scale, a new and valid anxiety instrument designed for critically ill patients, is now available.

The STAI is a unidimensional instrument with two 20-item subscales.<sup>59</sup> One subscale measures state anxiety, the other trait anxiety. For the state anxiety subscale, responses range from 1 (not at all) to 4 (very much so). Nurses, physicians, and other allied health professionals have used the STAI in numerous clinical practice and research settings.

The BSI is a 53-item multidimensional instrument that includes nine symptom dimensions, including anxiety.<sup>75</sup> The 6-item anxiety subscale addresses symptoms that are commonly associated with elevated anxiety, but does not include physiologic indices. Response options for each anxiety subscale item range from 0 (not at all) to 4 (extremely).

The Hospital Anxiety and Depression Scale (HADS) is a multidimensional instrument.<sup>76</sup> The 7-item anxiety subscale assesses anxiety without focusing on somatic symptoms. Response options range from 0 to 3, but differ. Unlike the STAI and BSI, normative data are not available for the HADS.

The POMS is a 65-item adjective rating scale of six affective dimensions, including tension-anxiety.<sup>77</sup> Response options range from 0 (not at all) to 4 (extremely). The POMS includes observable psychomotor manifestations of anxiety such as shakiness and restlessness.

The newly developed Faces Anxiety Scale is a unidimensional instrument that consists of five facial expressions ranging from a neutral expression to an expression showing extreme anxiety.<sup>78</sup> The Faces Anxiety Scale was designed to measure state anxiety; the patient simply selects the expression that best represents his or her present anxiety level. Scores range from 1 to 5; higher scores indicate higher anxiety. The Faces Anxiety Scale is less burdensome to patients than longer or more cognitively demanding instruments.<sup>78</sup> In a recent study, significantly more

adult ICU patients could respond to the Faces Anxiety Scale than to either the BSI or a visual analog anxiety scale.<sup>78</sup> Evidence suggests that the Faces Anxiety Scale is a valid measure of anxiety for adult ICU patients with a variety of medical and surgical admission diagnoses.<sup>79</sup>

Critical care nurses tend to focus on physiologic markers of anxiety. Critical care nurses identified agitation, increased blood pressure, and increased heart rate as the three most important indicators of anxiety.<sup>80</sup> In another study, critical care nurses indicated that they assessed anxiety most often by using behavioral and physiological indicators of anxiety.<sup>81</sup> Of the physiological indicators, nurses were most likely to use increases in heart rate, blood pressure, and respiratory rate as signs of anxiety. Remarkably, fewer than 5% of nurses indicated that the patient's verbalization of anxiety was an important component of their anxiety assessment.

However, physiologic symptoms of anxiety may not be important when assessing critically ill patients for anxiety,<sup>82</sup> because it can be challenging to distinguish between indicators of anxiety and signs that reflect changes in the patient's overall physical condition. Anxiety is not necessarily accompanied by physiologic changes; critically ill patients may exhibit anxiety in diverse manners.<sup>81</sup> In two recent studies, anxiety levels of ICU patients were not associated with blood pressure or heart rate.<sup>79,83</sup> Nor did participants in other studies manifest changes in heart rate and blood pressure in response to acute anxiety.<sup>84-86</sup> Even individuals with extreme anxiety did not respond in a predictable manner in that some, but not all, had a higher heart rate and blood pressure.<sup>87</sup> When anxiety was associated with an increased heart rate and blood pressure,<sup>88,89</sup> the increases were so minimal that nurses either would not observe the change or would not necessarily attribute the change to anxiety.



***Indicator of Anxiety in the AACN Sedation Assessment Scale***

The Faces Anxiety Scale<sup>78</sup> is the selected indicator of anxiety for use in the AACN Sedation Assessment Scale (Table 1). Use of a simple, straightforward, and valid self-report measure is crucial, given the need to minimize patient burden and given the poor relationship between patient-generated and clinician-generated anxiety ratings.<sup>90,91</sup> It is especially important to use brief and simple scales when conducting frequent anxiety assessments, as is the case for ICU patients.<sup>92</sup> Anxiety is a subjective experience; therefore, an anxiety assessment is inappropriate for patients who are unable to communicate their perceptions by either verbally stating which “face” pertains to them or pointing to a “face.”

**Sleep**

Sleep is a multifaceted domain that is challenging to achieve and measure, particularly in critically ill, sedated patients. For the purpose of the AACN Sedation Assessment Scale, sleep is defined as a complex cycle of physiological activities that occur during reduced consciousness in an environment that minimizes arousals or awakenings.

There are two physiologic periods of sleep: rapid eye movement (REM) and non-REM (NREM). Rapid eye movement sleep accounts for about 25%, whereas NREM sleep accounts for about 75% of sleep time.<sup>93</sup> In healthy people, REM sleep cycles with NREM sleep every 90 minutes.<sup>93</sup> Rapid eye movement sleep, considered essential for psychological and emotional well-being, involves rapid eye movements, irregular respiration and heart rate, and paralysis of major muscle groups except the diaphragm and upper airway muscles. Non-REM sleep progresses through four stages, from sleep onset to an increased proportion of slow-wave EEG patterns in the third and fourth stages wherein energy conservation, body renewal, and tissue building occur. The third and fourth stages of NREM are thus considered the most restorative

stages of sleep. Unfortunately, REM sleep and stages 3 and 4 of NREM sleep are often decreased or absent in patients in the ICU.<sup>94</sup>

Individual, environmental, and pharmacological factors impact the sleep of critically ill patients (Figure 1). Individual factors that disturb sleep include pain, mechanical ventilation, and severe sepsis.<sup>95-98</sup> Goals of comfort and patient-ventilator synchrony may need to be achieved before evaluating the effects of sedation on sleep. In patients with severe sepsis who did not receive continuous sedation 24 hours prior to study, EEG patterns remained the same while their eyes were open or closed; no definitive sleep or wake states were identifiable.<sup>96</sup>

The ICU environment often is not conducive to sleep. Critical care units involve noise, bright lights, and bustling activity that may be unavoidable during intensive, emergent situations. Such an environment creates a context for disturbed sleep despite adequate sedation management.

Pharmacological measures for sedation, analgesia, and other common conditions encountered in critical care may hinder, rather than promote, sleep. Critically ill patients who receive low to moderate doses of intermittent sedation or analgesia frequently experience severe disturbances in sleep architecture. Disturbances include fragmented sleep, reduced or absent REM and slow wave sleep, and a disrupted 24-hour circadian cycle.<sup>96,99,100</sup> Little is known about how doses of continuous, nocturnal, or heavy sedation impact physiological sleep. Critically ill patients who received a hypnotic or sedative during the night reported worse sleep than critically ill patients who did not receive a hypnotic or sedative during the night;<sup>101</sup> however, it is difficult to discern whether patients' reports reflected poor sleep before or after the medication. Critically ill patients' perceived quality of sleep did not improve significantly after nocturnal sedation with midazolam or propofol, but polysomnography was not measured.<sup>102</sup>

*Assessment of Sleep*

Polysomnography, the reference standard for measuring physiological sleep activities, remains an ideal, but impractical, indicator of sleep in critical care patients.

Electroencephalograph, electromyograph, and electrooculograph recordings graphically depict REM and NREM sleep. Knowledge about physiological activities derived from polysomnography underscores the importance of sleep as a distinct domain. Cyclic periods of REM and NREM activities confirm sleep as more than a composite score of consciousness and agitation domains because sleep involves physiological behaviors that protect, restore, and conserve body functions.

Bispectral index values used to monitor sedation levels are an unreliable indication of sleep, as BIS values vary widely within each sleep stage.<sup>103</sup> A BIS threshold value indicated the onset of sleep in healthy unsedated volunteers;<sup>104</sup> however, such a threshold in sedated patients may reflect onset of sedation<sup>105</sup> but not onset of sleep. Thus, although BIS values have been found to correlate with wakefulness in the validation of a sedation-agitation scale,<sup>47</sup> the adequacy of sedation should not be equated with successful attainment of sleep.

Although nurses routinely differentiate between patients' sleep and wake behaviors, nurses' assessments alone may not approximate the depth and quality of sleep in critically ill patients. Nurses' observations of awakening from sleep correlated with polysomnograph recordings of awakening, enhancing the validity of nurses' ability to differentiate wake from sleep behaviors.<sup>99</sup> Similarly, in another study, nurses observed sleep/wake status accurately in critically ill patients about 82% of the time when compared with polysomnograph recordings coded simply as "awake" or "asleep".<sup>106</sup> However, because REM and NREM stages were not analyzed in relation to nurses' observations, conclusions could not be drawn about whether

nurses' assessment of sleep approximate the physiologic depth and quality of sleep. In a separate, small study of nine patients recovering from major surgery, nurses' observations overestimated sleep as compared with REM and NREM sleep stages.<sup>107</sup> Consequently, sleep assessment remains incomplete if nurses' observations are relied on as the only indicator.

Patients' perceptions about their sleep offer an additional indicator to evaluate sleep as an outcome of sedation. Critically ill patients repeatedly report poor quality sleep.<sup>94,101,108</sup> Several aspects of perceived sleep can be measured, such as sleep depth, effectiveness, awakenings, and return to sleep.<sup>109</sup> Patients' perceived quality of sleep effectiveness was inversely associated with the extent of sleep disturbances from environmental factors.<sup>108</sup> Patients reported interruptions such as sudden increased noise, lights, and loud conversation as disturbing to sleep.<sup>95</sup> Patients' perceived awakenings were associated with polysomnograph awakenings lasting longer than 4 minutes.<sup>99</sup> Yet, perplexingly, noise and patient care-related interruptions accounted for less than one-third of arousals and awakenings in polysomnograph recordings of critically ill patients (sedation protocol unclear).<sup>110</sup> However, the investigators<sup>110</sup> did not report other factors that could have interrupted sleep, such as sudden changes in lights.

### ***Indicators of Sleep in the AACN Sedation Assessment Scale***

Clinical indicators of sleep for the AACN Sedation Assessment Scale (Table 1) include nurses' observations of sleep behavior and patients' perceived quality of sleep. These indicators arise from a framework of individual, environmental, and pharmacological factors that may impact sleep in critical care units and confound goal achievement (Figure 1). Nurses observe sleep through an assessment of the patient's physical appearance over time. Patient-perceived quality of sleep represents an overall measure suitable for a clinical assessment scale. For brevity, patients rate whether they slept well, fair, or poorly. Pictures may be used for patients

who have difficulty with language or verbal communication. The use of these practical and research-based indicators should enhance convergent validity regarding the impact of sedation on sleep.

### **Patient-Ventilator Synchrony**

Patient-ventilator synchrony is present when the inspiratory and expiratory phases of the patient and ventilator occur in a coordinated manner. During the inspiratory phase, synchrony occurs when the patient either accepts a mandatory mechanical breath or initiates a spontaneous breath that is in phase with the ventilator breath inspiratory time period. The patient's chest wall is relaxed; thus, it rises on inspiration, allowing gases to flow in freely with minimal resistance. During the expiratory phase of mechanical ventilation, synchrony is evident when the patient passively exhales and the chest falls.

Dyssynchronous patient-ventilator breathing may result secondary to the gas flow setting being insufficient to meet the patient's inspiratory demand. In this condition, which may occur with mandatory or spontaneous breathing modes, the peak inspiratory flow requirement results in a greatly increased muscle workload. Conditions such as auto-PEEP (i.e., incomplete exhalation) result in inadequate ventilator sensing and thus increased patient effort to "trigger" a spontaneous breath. Chest movement appears extreme and is not coordinated with ventilator cycling. During the expiratory phase of ventilation, an expiratory time that precludes complete exhalation or is too long, thus interfering with a spontaneous inspiration, may result in dyssynchrony. Forceful or extreme inspiratory or expiratory chest movements, frequent or sustained coughing, and/or chest wall muscle tightening during any phase of the ventilatory cycle all evidence dyssynchrony. Consequently, dyssynchrony causes inadequate gas exchange,

hemodynamic instability, and patient distress. In addition, resistance to flow increases peak airway pressure, placing patients at risk for ventilator-induced lung injury.

Selected pressure- and volume-targeted ventilator modes, flow delivery options, and spontaneous breath triggering mechanisms promote improved patient-generated breathing, mimic more physiologic breathing patterns, and enhance patient comfort. Efficient use of these options may help patients adapt to the ventilator or achieve complete ventilatory control, and thereby reduce or eliminate the need for deep sedation. Nonetheless, sedation is often necessary to facilitate mechanical ventilation and may be integral to management of patients with severe respiratory failure.<sup>111,112</sup>

Patient-ventilator dyssynchrony should prompt clinicians to perform a rapid, systematic assessment of the patient and ventilator to identify the cause of distress.<sup>113-115</sup> Once problems are identified and ventilator settings are optimized, clinicians still may need to administer sedatives to improve synchrony. The goal of sedation therapy is to promote a state of patient-ventilator harmony where the patient responds in a coordinated fashion to ventilator breaths, whether they are mandatory or patient generated. This approach prevents excessive and non-productive muscle work and promotes eventual ventilator liberation.

The use of continuous sedative infusions is associated with prolonged duration of mechanical ventilation,<sup>116-118</sup> ICU length of stay,<sup>116-118</sup> and hospital length of stay.<sup>117</sup> Daily interruption of sedative infusions and the use of nurse-managed algorithms for sedation administration appear to prevent over-sedation and improve outcomes in these patients. Prolonged mechanical ventilation may predispose patients to ventilator associated pneumonia, lung injury, and other complications related to the presence of an artificial airway.<sup>119</sup>

The effect of sedation on outcomes of mechanical ventilation and weaning has spawned discussion about the best method to ensure that the patient is maintained at the lightest level of sedation. As a result of these concerns, concepts such as the “daily interruption” or “sedation vacation” and “continuous titration to lowest dose” are becoming more formalized.<sup>16</sup> Kress and colleagues reported that daily interruption of sedative infusions was associated with shorter duration of both mechanical ventilation and ICU length of stay.<sup>118</sup> However, caution is warranted as insufficient sedation may precipitate patient-ventilator dyssynchrony and associated physiologic alterations in thoracic pressures and gas exchange. Inadequate sedation is also associated with unplanned extubation.<sup>120</sup>

Weinert and colleagues conducted focus group interviews of nurses to determine factors affecting nurses’ delivery of sedative therapy.<sup>121</sup> Nurses identified improved patient-ventilator synchrony as a goal of sedation and considered oversedation a possibility when patients did not initiate spontaneous breaths at a rate greater than the set ventilator rate. Weinert’s work demonstrates that nurses recognize the relationship between sedation management and optimal ventilator outcomes.

### ***Assessment of Patient-Ventilator Synchrony***

De Jonghe and colleagues reviewed sedation instruments and determined that patient-ventilator synchrony is one of the most frequently assessed aspects of sedation.<sup>122</sup> Many instruments have been designed for research investigations where the purpose is to compare sedative medications or to assess the effectiveness of a sedative regimen. These instruments address pattern of breathing,<sup>123</sup> evidence of spontaneous respiratory effort,<sup>124</sup> physiologic responses such as compromised oxygenation or ventilation,<sup>125</sup> cough,<sup>29,126</sup> and patient-ventilator synchrony.<sup>29,39,126,127</sup>

Hartwig and colleagues developed a sedation assessment instrument to evaluate the effectiveness of midazolam for intubated pediatric patients.<sup>127</sup> Although their respiration subscale includes the ideal indicators of synchrony and spontaneous breathing, reliability and validity data are unavailable.

The COMFORT Scale is a valid and reliable scale that was developed to assess efficacy of pharmacologic and psychological interventions used to reduce distress in intubated pediatric patients.<sup>29</sup> To construct the scale, the authors reviewed the literature regarding pediatric distress and surveyed critical care nurses about variables used to assess patient distress. The respiratory response subscale includes the indicators of spontaneous respiration, coughing, choking, and resistance to ventilation. The Pearson interrater reliability coefficient for the respiratory response subscale was .70, indicating that clinicians had some difficulty discriminating among the levels.

***Indicator of Patient-Ventilator Synchrony in the AACN Sedation Assessment Scale***

The indicator for measuring patient-ventilator synchrony is breathing pattern relative to the ventilator cycle (Table 1). Implied within patient-ventilator synchrony is that the patient may initiate spontaneous breaths. Therefore, the ventilator synchrony indicator of the AACN Sedation Assessment Scale incorporates assessment of spontaneous breathing. It also includes assessment of the pattern of breathing to determine patient-ventilator concordance. The literature does not contain reliable and valid scales for measuring patient-ventilator synchrony in adults; therefore, indicators from two pediatric instruments<sup>29,127</sup> were adapted for the AACN Sedation Assessment Scale. A three-level indicator was chosen to enhance clinicians' discrimination among the levels.



## **Additional Elements of the AACN Sedation Assessment Scale**

Prior to using any sedation assessment scale, it is important that clinicians assess and treat potential physiological causes of patient distress or agitation. For example, hypoxemia, pneumothorax, ventilatory failure, and hypoperfusion cause patient distress and hemodynamic instability that will be refractory to sedation therapy. Pain should also be assessed with a valid and reliable scale and treated before proceeding with sedation assessment.

Another important precursor to sedation assessment is identifying the goals of sedation management. Members of the multidisciplinary team should identify the goals of sedation therapy, which can then be used to guide titration of sedative agents. Common goals of sedation therapy are to alleviate agitation, prevent self-harm, facilitate patient-ventilator synchrony, relieve anxiety, promote sleep/rest, induce amnesia, promote hemodynamic stability, and reduce intracranial pressure. The directions that accompany the AACN Sedation Assessment Scale will remind clinicians to assess pain and identify the goals of sedation management before assessing sedation.

## **Next Steps**

At present, the AACN Sedation Assessment Scale is not ready for use in clinical practice. The next step in development of the AACN Sedation Assessment Scale, Phase 3, is to conduct large, rigorous clinical trials to test the reliability and validity of the scale in various diagnostic groups and patient care situations common in critical care. Given the need to test the scale, details regarding how to score, interpret, and document the sedation assessment are beyond the scope of this paper, but will be described in future publications. Funding is currently being pursued to support the clinical trials needed to test the AACN Sedation Assessment Scale.

In addition to determining the validity and reliability of the proposed scale, data from the clinical trials will help identify which of the scale's five domains are required for sedation assessment based on the sedation goal(s) selected. Some domains (for example, consciousness or agitation) may need to be assessed regardless of which sedation goal(s) is selected, while other domains (for example, patient-ventilator synchrony) may require assessment only for specific sedation goals.

The results of clinical trials may also elucidate the need for additional domains. For instance, although the AACN Sedation Assessment Scale does not include hemodynamic parameters, there is debate about whether physiologic stability should be a separate domain.

Finally, during clinical testing of the scale, information will be obtained to determine whether delirium should be assessed prior to, or following, sedation assessment and treatment. Delirium in critically ill patients is common but may be difficult to differentiate from behaviors that indicate the need for sedation therapy. The treatment of delirium requires use of neuroleptic drugs, such as haloperidol and chlorpromazine, not sedatives. No data are available to guide a recommendation on whether delirium assessment and management should occur prior to, or following, sedation assessment and management.

## **Summary / Conclusions**

In summary, critical care experts propose a new sedation assessment scale, the AACN Sedation Assessment Scale, which consists of five domains – consciousness, agitation, sleep, anxiety, and patient-ventilator synchrony. A major advantage of the AACN Sedation Assessment Scale is that its domains parallel common goals of sedation therapy. The proposed measurements for each domain are based on a comprehensive evaluation of the science and expert recommendations. Prior to widespread use of the AACN Sedation Assessment Scale, clinical testing is required to determine its validity and reliability in a variety of critically ill patient care situations.

### **Summary of Key Points**

Clinicians commonly sedate critically ill patients. Sedatives should be administered to achieve predetermined endpoints. Most currently available sedation assessment scales are inadequate because they focus on a single domain, such as consciousness. In this paper, the authors describe the development of the AACN Sedation Assessment Scale. This new scale consists of five domains – consciousness, agitation, anxiety, sleep, and patient-ventilator synchrony. A major advantage of the AACN Sedation Assessment Scale is that its domains parallel common goals of sedation therapy for critically ill patients. The proposed measurements for each domain are based on a comprehensive evaluation of the science and expert recommendations. Prior to widespread use of the AACN Sedation Assessment Scale, clinical testing is required to determine its validity and reliability in a variety of critically ill patient care situations.

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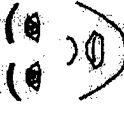
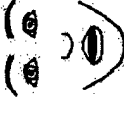
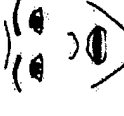
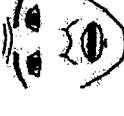
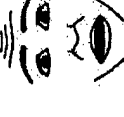
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Table 1 AACN Sedation Assessment Scale

Domain / Subscale	Indicator	Best 1	2	3	4	5 Worst
Consciousness	Awake and aware of self and environment	Spontaneously opens eyes and initiates interaction with others.	Wakens and responds after light verbal or tactile stimuli. May return to sleep when stimuli stops.	Wakens and responds after strong or noxious verbal or tactile stimuli. Returns to sleep when stimuli stops.	Displays localization or withdrawal behaviors to noxious stimuli.	Does not waken to strong or noxious stimuli.
Agitation	Body Movement – Patient / Staff Safety*	Calm body movements and tolerant of treatments and restrictions. Movements do not pose a significant risk for patient or staff safety.		Body movements or noncompliance with treatments or restrictions do not pose a significant risk for patient or staff safety.		Body movements or noncompliance with treatments or restrictions pose a significant risk for patient or staff safety.
	Patient Noise	No noises.		Frequent moaning or calling out.		Shouting, screaming, or other disruptive vocalizations.
	Patient statements**	Very calm.				Very restless.
Sleep	Observed Sleep	Looks asleep, calm, resting (eyes closed, calm face & body).	Looks asleep, periodically awakens and returns to sleep easily.	Awake, naps occasionally for brief periods.		Unable to sleep or nap.
	Patient Perceived Quality of Sleep**	“I slept well.” 		“I slept fair.” 		“I slept poorly.” 
Anxiety	Patient Perceived Anxiety (Faces Anxiety Scale)*	No Anxiety. 				Extreme Anxiety. 
Patient-Ventilator Synchrony	Breathing pattern relative to ventilator cycle	Synchrony of patient and ventilator at all times, cooperative and accepting ventilation. Coordinated, relaxed		Occasional resistance to ventilation, or spontaneous breathing is out of synchrony with the ventilator. Chest movement		Patient frequently resisting ventilation, or spontaneous breathing not synchronous with the ventilator. Uncoordinated

# Sedation Assessment Scale

Domain / Subscale	Indicator	Best	1	2	3	4	5	Worst
		chest movement.			occasionally not coordinated with ventilator.		chest and ventilator movements.	

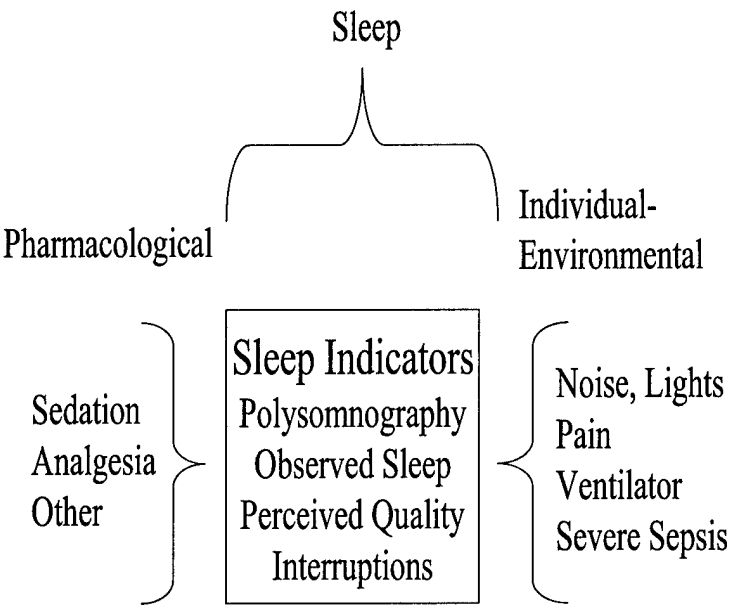
\* This component assessed in all patients, regardless of the goal of sedation.

\*\* Assumes the ability to understand directions and communicate their perceptions either verbally, in writing, or by pointing to words/pictures. If score is greater than 2 for this subscale, ask the patient if they need something to help them relax.

Figure Legend

**Figure 1** Organizing framework for the impact of sedation on sleep

Figure 1



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